

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Rafael Andino, Christopher Brooks, and
Donald Van Royen

Application No. : Not yet assigned

Filed : July 15, 2003

For : APPARATUS AND METHODS FOR FACILITATING
WOUND HEALING

Group Art Unit : Not yet assigned

Examiner : Not yet assigned

Hon. Commissioner for Patents
Post Office Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. §§ 1.56 and 1.97,
applicants wish to call the attention of the Examiner to the
following documents:

U.S. Patents

Caesar	2,099,511	(11/16/37)
Horn	3,918,459	(11/11/75)
Ellis et al.	3,964,477	(06/22/76)
Ellis	4,019,510	(04/26/77)
Konikoff	4,142,521	(03/06/79)
Fairbanks	4,233,965	(11/18/80)
Donadelli	4,312,340	(01/26/82)
Greatbatch	4,313,438	(02/02/82)
Greatbatch	4,314,554	(02/09/82)
Wilson	4,398,545	(08/16/83)
Bryan	4,509,535	(04/09/85)
Brighton et al.	4,535,775	(08/20/85)
Maurer	4,556,051	(12/03/85)
Ibbott	4,619,252	(10/28/86)

U.S. Patents (cont'd)

Fuxue et al.	4,846,178	(07/11/89)
Miller	4,846,181	(07/11/89)
Takeuchi et al.	4,895,153	(01/23/90)
Bartelt et al.	4,895,154	(01/23/90)
Jones	4,911,688	(03/27/90)
Takeuchi et al.	4,922,906	(05/08/90)
Claude	4,982,742	(01/08/91)
Keusch et al.	4,989,607	(02/05/91)
Rogozinski	5,395,398	(03/07/95)
D'Alerta	5,423,874	(06/13/95)
Zanakis et al.	5,433,735	(07/18/95)
Scherson et al.	5,578,022	(11/26/96)
Becker et al.	5,814,094	(09/29/98)
Rise	5,853,424	(12/29/98)
Shoemaker, II	5,974,344	(10/26/99)
Kozhemiakin et al.	6,122,550	(09/19/00)
Millot et al.	6,411,853	(06/25/02)

Foreign Patents

PCT	WO 00/65993	11/09/00
EPO	EP 0 947 214 A3	10/06/99
PCT	WO 98/26838	06/25/98

Other Documents

Assimacopoulos, Dennis, "Low Intensity Negative Electric Current in the Treatment of Ulcers of the Leg Due to Chronic Venous Insufficiency," *American Journal of Surgery*: 115, 683-687 (1968).

Baker, Lucinda L., et al., "Effects of Electrical Stimulation on Wound Healing in Patients with Diabetic Ulcers," *Diabetes Care*: 20(3), 405-412 (1997).

Biedebach, Mark C., "Accelerated Healing of Skin Ulcers by Electrical Stimulation and the Intracellular Physiological Mechanisms Involved," *Acupuncture and Electro-therapeutics Research*: 14(1), 43-60 (1989).

Carley, Patrick J., et al., "Electrotherapy for Acceleration of Wound Healing: Low Intensity Direct Current," *Arch. Phys. Med. Rehab.*: 66, 443-446 (1985).

Davis, Stephen C., et al., "Electrical Stimulation and Ultrasound in Wound Healing," *Dermatologic Clinics*: 11(4), 775-781 (1993).

Dayton, Paul D., et al., "Electrical Stimulation of Cutaneous Ulcerations A Literature Review," *Journal of the American Podiatric Medical Association*: 79(7), 318-321 (Jul. 1989).

Feedar, Jeffrey A., et al. "Chronic Dermal Ulcer Healing Enhanced with Monophasic Pulsed Electrical Stimulation," *Physical Therapy*: 71(9), 639-649 (1991).

Fleischli, John G., et al. "Electrical Stimulation in Wound Healing," *The Journal of Foot & Ankle Surgery*: 36(6), 457-461 (1997).

Gault, Walter R., et al. "Use of Low Intensity Direct Current in Management of Ischemic Skin Ulcers," *Physical Therapy*: 56(3), 265-269 (March 1976).

Gentzkow, Gary D., et al., "Electrical Stimulation for Dermal Wound Healing," *Clinics in Podiatric Medicine and Surgery*: 8(4), 827-841 (1991).

Gentzkow, Gary D., "Electrical Stimulation to Heal Dermal Wounds," *Journal of Dermatologic Surgery and Oncology*: 19(8), 753-758 (Aug. 1993).

Gilcreast, Darlene M., et al., "Effect of Electrical Stimulation on Foot Skin Perfusion in Persons with or at Risk for Diabetic Foot Ulcers," *Wound Repair and Regeneration*: 6(5), 434-441 (1998).

Gogia, Prem P., "Physical Therapy Modalities for Wound Management," *Ostomy/Wound Management*: 42(1), 46-54 (1996).

Itoh, Masayoshi, et al., "Accelerated Wound Healing of Pressure Ulcers by Pulsed High Peak Power Electromagnetic Energy (Diapulse)," *Decubitus*: 4(1), 24-34 (1991).

Kloth, Luther C., "Physical Modalities in Wound Management: UVC, Therapeutic Heating and Electrical Stimulation," *Ostomy/Wound Management*: 41(5), 18-27 (1995).

Kloth, Luther C., et al., "Promotion of Wound Healing with Electrical Stimulation," *Advances in Wound Care*: 9(5), 42-45 (Sept./Oct. 1996).

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Lee, Raphael C., et al., "A Review of the Biophysical for the Clinical Application of Electric Fields in Soft-Tissue Repair," *Journal of Burn Care and Rehabilitation*: 14(3), 319-335 (May/June 1993).

Lundeberg, Thomas C.M., et al., "Electrical Nerve Stimulation Improves Healing of Diabetic Ulcers," *Annals of Plastic Surgery*: 29(4), 328-331 (1992).

Nicolle, Frederick V., et al., "Use of Radio-Frequency Pulsed Energy in the Control of Postoperative Reaction in Blepharoplasty," *Aesthetic Plastic Surgery*: 6, 169-171 (1982).

Rowley, Blair A., et al., "The Use of Low Level Electrical Current for Enhancement of Tissue Healing," *Biomedical Sciences Instrumentation*: 1, 111-114 (1974).

Šemrov, Deján, et al., "DC Electrical Stimulation for Chronic Wound Healing Enhancement. Part 2. Parameter Determination by Numerical Modelling," *Bioelectrochemistry and Bioenergetics*: 43:271-277 (1997).

Stefanovska, A., et al., "Treatment of Chronic Wounds by means of Electric and Electromagnetic Fields - Part 2: Value of FES Parameters for Pressure Sore Treatment," *Medical & Biological Engineering & Computing*: 31(3), 213-220 (May 1993).

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Weiss, Darryl S., et al., "Electrical Stimulation and Wound Healing," *Arch Dermatology*: 126, 222-225 (Feb. 1990).

Wheeler, Paul C., et al., "Neural Considerations in the Healing of Ulcerated Tissue by Clinical Electrotherapeutic Application of Weak Direct Current: Findings and Theory," *Neuroelectric Research*: 9, 83-99 (1971).

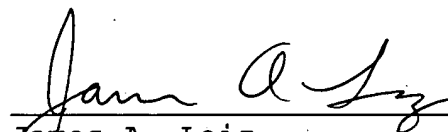
Wolcott, Lester E., "Accelerated Healing of Skin Ulcers by Electrotherapy: Preliminary Clinical Results," *Southern Medical Journal*: 62, 795-801 (July 1969).

Yarkony, Gary M., "Pressure Ulcers: A Review," *Archives of Physical Medicine and Rehabilitation*: 75(8), 908-917 (1994).

These documents are listed on the accompanying Form
PTO-1449 (submitted in duplicate) and copies are enclosed
herewith.

Consideration of the foregoing in relation to this
patent application is respectfully requested.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "James A. Leiz", is written over a horizontal line.

James A. Leiz
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New York, New York 10020-1104
Tel.: (212) 596-9000

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANTS	ATTY. DOCKET NO. BIO-001 DIV.	APPLICATION NO. To be assigned
	APPLICANTS Rafael Andino et al.	
	FILING DATE July 15, 2003	GROUP

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	2,099,511	11/16/37	Caesar	188	408	
	3,918,459	11/11/75	Horn	128	419R	
	3,964,477	06/22/76	Ellis et al.	128	172.1	
	4,019,510	04/26/77	Ellis	128	172.1	
	4,142,521	03/06/79	Konikoff	128	82.1	
	4,233,965	11/18/80	Fairbanks	128	1.5	
	4,312,340	01/26/82	Donadelli	128	207.21	
	4,313,438	02/02/82	Greatbatch	128	207.21	
	4,314,554	02/09/82	Greatbatch	128	207.21	
	4,398,545	08/16/83	Wilson	128	798	
	4,509,535	04/09/85	Bryan	128	798	
	4,535,775	08/20/85	Brighton et al.	128	419	
	4,556,051	12/03/85	Maurer	128	1.5	
	4,619,252	10/28/86	Ibbott	128	82.1	
	4,846,178	07/11/89	Fuxue et al.	128	419F	
	4,846,181	07/11/89	Miller	128	421	
	4,895,153	01/23/90	Takeuchi et al.	128	421	
	4,895,154	01/23/90	Bartelt et al.	128	421	
	4,911,688	03/27/90	Jones	604	20	
	4,922,906	05/08/90	Takeuchi et al.	128	419R	
	4,982,742	01/08/91	Claude	128	798	
	4,989,607	02/05/91	Keusch et al.	128	640	
	5,395,398	03/07/95	Rogozinski	607	50	
	5,423,874	06/13/95	D'Alerta	607	72	
	5,433,735	07/18/95	Zanakis et al.	607	50	
	5,578,022	11/26/96	Scherson et al.	604	304	
	5,814,094	09/29/98	Becker et al.	607	50	
	5,853,424	12/29/98	Rise	607	117	

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 EV 132183149 US

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	5,974,344	10/26/99	Shoemaker, II	607	149	
	6,122,550	09/19/00	Kozhemiakin et al.	607	101	
	6,411,853	06/25/02	Millot et al.	607	50	

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	WO 00/65993	11/09/00	PCT				
	EP 0 947 214 A2	10/06/99	EPO				
	WO 98/26838	06/25/98	PCT				

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